

WHAT IS CLAIMED IS:

1. A method of elevating intraductal carotenoid levels in a non lactating breast in a patient, comprising the steps of removing intraductal breast fluid from the non lactating breast at least once every other day for at least five days.
- 5 2. A method of elevating intraductal carotenoid levels in a non lactating breast as in Claim 1, wherein the removing step comprises manual aspiration.
3. A method of elevating intraductal carotenoid levels in a non lactating breast as in Claim 1, wherein the removing step comprises the steps of applying suction and compression.
- 10 4. A method of elevating intraductal carotenoid levels in a non lactating breast as in Claim 3, further comprising the step of applying heat to the breast.
5. A method of elevating intraductal carotenoid levels in a non lactating breast as in Claim 3, wherein the compression comprises peristaltic compression.
6. A method of elevating intraductal carotenoid levels in a non lactating breast as in Claim 3, further comprising the step of increasing the oxytocin level in the breast prior to the removing step.
- 15 7. A method of elevating intraductal carotenoid levels in a non lactating breast as in Claim 6, wherein the increasing the oxytocin level step is accomplished by administering oxytocin to the patient.
- 20 8. A method of elevating intraductal carotenoid levels in a non lactating breast as in Claim 6, wherein the increasing the oxytocin level step is accomplished by nipple stimulation.
9. A method of elevating intraductal carotenoid levels in a non lactating breast as in Claim 1, wherein intraductal fluid is removed on at least two occasions over a period of no more than about two months.
- 25 10. A method of removing intraductal breast fluid from a patient, comprising the steps of contacting the breast with a mechanical intraductal fluid aspiration device, and activating the device to apply peristaltic compression and suction to the breast during a period of non lactation to remove intraductal breast fluid.
- 30 11. A method of removing intraductal breast fluid as in Claim 10, further comprising the step of applying heat from the device to the breast.

12. A method of removing intraductal breast fluid as in Claim 10, wherein the removing step is repeated at least once.

13. A method of removing intraductal breast fluid as in Claim 10, wherein the patient is parous and at least three months post wean.

5 14. A method of removing intraductal breast fluid as in Claim 10, wherein the patient is nulliparous.

15. A method of reducing the risk of cancer formation in the breast duct, comprising the steps of periodically removing intraductal breast fluid from the breast using a mechanical intraductal breast fluid removal device to maintain an elevated
10 average carotenoid level in the breast fluid compared to the carotenoid level in the absence of intraductal breast fluid removal.

16. A method of reducing the risk of cancer formation in the breast duct as in Claim 15, wherein the elevated average carotenoid level is maintained for a period of at least thirty days.

15 17. A method of reducing the risk of cancer formation in the breast duct as in Claim 15, wherein the elevated average carotenoid level is at least about 105% of the average blood serum carotenoid level for the patient taken over the time of the periodically removing step.

18. An intraductal breast fluid aspiration device, comprising:
20 a tissue contacting surface defining a first concavity for receiving a breast and a second concavity for receiving a nipple;
a driver, for imparting compressive force on at least the portion of the tissue contacting surface defining the first concavity;
a vacuum conduit in communication with the second concavity; and
25 a sample collector in communication with the second concavity.

19. An intraductal breast fluid aspiration device as in Claim 18, wherein the driver imparts peristaltic compressive force on the tissue contacting surface.

20. An intraductal breast fluid aspiration device as in Claim 18, further comprising a heat source thermally coupled to the tissue contacting surface.

30 21. An intraductal breast fluid aspiration device as in Claim 18, wherein the driver comprises a motor.

22. An intraductal breast fluid aspiration device as in Claim 18, wherein the driver comprises at least one expandable chamber.

23. An intraductal breast fluid aspiration device as in Claim 22, wherein the chamber is defined within a flexible tube.

5 24. An intraductal breast fluid aspiration device as in Claim 18, further comprising a vacuum source in communication with the vacuum conduit.

25. An intraductal breast fluid aspiration device as in Claim 18, wherein the sample collector comprises a hollow container.

10 26. An intraductal breast fluid aspiration device as in Claim 25, wherein the container is removable from the aspiration device.

27. An intraductal breast fluid aspiration device as in Claim 18, wherein the sample collector comprises an absorbent media.

15 28. An intraductal breast fluid aspiration device as in Claim 18, wherein the sample collector comprises a binding system for binding at least one analyte of interest in the breast fluid.

29. An intraductal breast fluid aspiration device as in Claim 28, wherein the binding system comprises a monoclonal antibody.

30. An intraductal breast fluid aspiration device as in Claim 18, further comprising a microprocessor for controlling the driver.

20 31. An intraductal breast fluid aspiration device as in Claim 18, further comprising a housing, wherein the tissue contacting surface is removably carried by the housing.

32. A portable, self contained, intraductal fluid aspiration device, comprising:

25 a housing;
a breast interface on the housing;
a vacuum source in communication with the interface;
a compression driver coupled to the interface; and
at least one control on the housing for controlling operation of the
30 aspiration device.

33. A portable, self contained, intraductal fluid aspiration device as in Claim 32, wherein the interface is removably connected to the housing.

34. A portable, self contained, intraductal fluid aspiration device as in Claim 32, further comprising a fluid reservoir in communication with the interface.

5 35. A portable, self contained, intraductal fluid aspiration device as in Claim 34, wherein the fluid reservoir is removably attached to the housing.

36. A portable, self contained, intraductal fluid aspiration device as in Claim 32, further comprising a heating element in thermal communication with the interface.

10 37. A portable, self contained, intraductal fluid aspiration device as in Claim 32, further comprising an ultrasonic transducer in communication with the interface.

38. An intraductal fluid aspiration device, comprising:

a control unit;

a power head;

a flexible control line connecting the power head to the control unit;

15 a disposable user interface removably attached to the power head;

a vacuum source in the control unit, in communication with the user interface through the control line; and

a compression cycle generator in force transmitting contact with the user interface.

20 39. An intraductal fluid aspiration device as in Claim 38, further comprising an ultrasound transducer in the power head.

40. An intraductal fluid aspiration device as in Claim 38, further comprising a central processing unit in the control unit for controlling the delivery of heat, compression and suction through the user interface.

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